

## ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES

1 17

IMPORTANT: Mark all packages and papers with contract and/or order numbers.


1. DATE OF ORDER 04/02/2020		2. CONTRACT NO. (If any) HHSO100201200004I		8. SHIP TO:	
3. ORDER NO. 75A50120F33006		4. REQUISITION/REFERENCE NO. OS256855		a. NAME OF CONSIGNEE Multiple Destinations	
5. ISSUING OFFICE (Address correspondence to) ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201				b. STREET ADDRESS	
				c. CITY	d. STATE e. ZIP CODE
7. TO:				f. SHIP VIA	
a. NAME OF CONTRACTOR EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC				8. TYPE OF ORDER	
b. COMPANY NAME				a. PURCHASE REFERENCE YOUR:	
c. STREET ADDRESS EMERGENT MANUFACTURING OPERATIONS B 5901 E LOMBARD ST				<input checked="" type="checkbox"/> b. DELIVERY Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.	
d. CITY BALTIMORE		e. STATE MD	f. ZIP CODE 212246824		
9. ACCOUNTING AND APPROPRIATION DATA 2020.199COV2.25103				10. REQUISITIONING OFFICE BARDA	
11. BUSINESS CLASSIFICATION (Check appropriate box(es)) <input type="checkbox"/> a. SMALL <input checked="" type="checkbox"/> b. OTHER THAN SMALL <input type="checkbox"/> c. DISADVANTAGED <input type="checkbox"/> d. WOMEN-OWNED <input type="checkbox"/> e. HUBZone <input type="checkbox"/> f. SERVICE-DISABLED <input type="checkbox"/> g. WOMEN-OWNED SMALL BUSINESS (WOSB) <input type="checkbox"/> h. EDWOSB <input type="checkbox"/> VETERAN-OWNED <input type="checkbox"/> ELIGIBLE UNDER THE WOSB PROGRAM					12. F.O.B. POINT

13. PLACE OF		14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date) 10/02/2021	16. DISCOUNT TERMS
a. INSPECTION Destination	b. ACCEPTANCE Destination			

## 17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Tax ID Number: (b)(4) DUNS Number: (b)(6) A detailed breakdown of CLIN costs is reflected in Section B of this task order. Appr. Yr.: 2020 CAN: 199COV2 Object Class: 25103 Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE	18. SHIPPING POINT		19. GROSS SHIPPING WEIGHT		20. INVOICE NO.		17(h) TOTAL (Cont. pages)
	21. MAIL INVOICE TO:						
	a. NAME PSC/FMS						\$14,531,801.00
	b. STREET ADDRESS (or P.O. Box) PSC_invoices@psc.hhs.gov						
c. CITY		d. STATE	e. ZIP CODE				17(i) GRAND TOTAL
						\$14,531,801.00	

22. UNITED STATES OF  
AMERICA BY (Signature)

**Crystal R. Reed-tweedy -S**
Digitally signed by Crystal R.  
Reed-tweedy -S  
Date: 2020.04.02 13:38:13 -04'00'23. NAME (Typed)  
CRYSTAL R. REED-TWEEDY  
TITLE: CONTRACTING/ORDERING OFFICER

**ORDER FOR SUPPLIES OR SERVICES**  
**SCHEDULE - CONTINUATION**

PAGE NO  
2

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER 04/02/2020	CONTRACT NO. HHS0100201200004I	ORDER NO. 75A50120F33006
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ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Period of Performance: 04/02/2020 to 10/02/2021					
1	ASPR-20-01770 -- Award of a Task Order to Emergent Product Development under Emergent's current CIADM IDIQ contract (HHS0100201200004I) to support Development of a COVID-19 Therapeutic Medical Countermeasure (COVID-HIG)  Delivery Location Code: HHS/OS/ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201 US Amount: \$14,531,801.00				(b)(4)	
2	OPTIONAL- Support of additional clinical trial, including the supply of at least (b)(4) doses, plus storage and shipping as required Amount: (b)(4) (Option Line Item)  Delivery Location Code: HHS HHS 200 Independence Avenue, SW Washington DC 20201 US Amount: (b)(4)  The total amount of award: (b)(4) The obligation for this award is shown in box 17(i).				0.00	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))

\$14,531,801.00

**B. COST / PRICE SCHEDULE**

**Cost-Plus-Fixed Fee CLINS**

<b><u>Base CLIN Table</u></b>				
<b><u>CLIN</u></b>	<b><u>ITEM DESCRIPTION</u></b>	<b><u>Cost</u></b>	<b><u>Fee (8%)</u></b>	<b><u>Cost Plus Fixed Fee</u></b>
0001	<ul style="list-style-type: none"> <li>Collection of human plasma containing antibodies to SARS-CoV-2 sufficient to supply at least 400 doses of drug product.</li> <li>cGMP manufacture of at least 400 doses of drug product for use in a controlled clinical trial; manufacturing approach must be amenable to commercial-scale production within potential EUA timeframe estimated to be 12 months; stability testing as needed to support clinical use.</li> <li>Development and validation/qualification of assays as required for screening, stability testing, and manufacturing.</li> <li>Supportive nonclinical studies as required for development of drug product.</li> <li>Regulatory filings to FDA, including formal interactions (e.g., Pre-IND) as necessary, IND submission, and EUA submission within targeted 12 months of task order award.</li> <li>Support of clinical trial through drug supply, including storage and shipping as required.</li> <li>Program management and reporting as required.</li> </ul>			



<u>Option CLIN Table</u>				
<u>CLIN</u>	<u>ITEM DESCRIPTION</u>	<u>Cost</u>	<u>Fee (8%)</u>	<u>Cost Plus Fixed Fee</u>
0002	<ul style="list-style-type: none"><li>Support of additional clinical trial, including the supply of at least 100 doses, plus storage and shipping as required.</li><li>Program management and reporting as required.</li></ul>			

**Total Not to Exceed Amount**

**C. STATEMENT OF OBJECTIVES**

**C.1 Background**

In December 2019, a novel (new) coronavirus known as SARS-CoV-2 ("the virus") was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19. As a result of the virus' global spread, HHS declared a public health emergency for the U.S. on January 31, 2020 to aid the nation's healthcare community in responding to COVID-19. On March 13, 2020, the President proclaimed that the COVID-19 outbreak in the U.S. constitutes a national emergency.

Currently, there are no FDA-approved therapeutics for the treatment of COVID-19. There is great interest in evaluating the use of convalescent plasma and plasma-derived products as therapeutics for COVID-19, given their historical use as treatments in other outbreaks. Notably, the FDA recently published guidance on the investigational use of COVID-19 convalescent plasma under emergency INDs.

As part of the HHS' response to COVID-19, BARDA is seeking solutions for the manufacture and development of plasma-derived polyclonal antibody-based COVID-19 therapeutics for clinical evaluation, with potential for commercial-scale manufacture under EUA.

**C.2 Scope of Work (SOW)/Objectives**

Independently and not as an agent of the US Government (USG), the Contractor shall furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities not otherwise provided by the USG as needed to perform the work described below.

The Contractor shall:

- Collect human plasma containing antibodies to SARS-CoV-2 sufficient to supply at least (b)(4) doses of drug product.
- Manufacture at least (b)(4) doses of cGMP drug product for use in a controlled clinical trial using an approach amenable to commercial-scale production within potential EUA timeframe of (b)(4) plus stability testing as required for clinical use. The clinical trial is anticipated to start within (b)(4) of contract award.
- Develop and validate/qualify assays required for screening, manufacturing, and stability testing as necessary.
- Conduct supportive nonclinical studies as required for development of drug product.
- Prepare and submit regulatory filings to FDA, including IND submission, and conduct formal meetings (e.g., Pre-IND) with FDA as necessary. EUA submission is targeted within (b)(4) of task order award.
- Support clinical trial(s) through the delivery of cGMP drug product (includes storage and shipping) and all supporting information as required.
- Provide program management and reporting as required.

### C.3 (SOW) Tasks

#### TASKS

The Contractor shall perform the following Tasks:

#### CLIN 0001: Manufacture and Development of Human Immune Globulin Drug Product from Human Plasma for Clinical Evaluation

##### A. Collection of Human Plasma Containing Antibodies to SARS-CoV-2

The Contractor shall collect human plasma containing antibodies to SARS-CoV-2 which will include utilizing FDA-approved plasma collection centers in the U.S. Collection may rely on a

(b)(4)  
(b)(4) The volume of plasma collected shall be sufficient to supply at least (b)(4) doses of final human immune globulin drug product.

##### B. Manufacture of at Least (b)(4) doses of Human Immune Globulin Drug Product

The Contractor shall use the collected plasma to manufacture at least (b)(4) doses of fill-finished human immune globulin final drug product under cGMP conditions. The manufacturing approach used should be scalable based on the availability and timing of plasma collections, with potential to scale-up to commercial manufacturing within a potential EUA timeframe of (b)(4) from task order award. A manufacturing process used previously for FDA-approved (b)(4)



human immune globulin products is preferred as a means of reducing technical and regulatory risk. The process should include purification and viral inactivation/removal as necessary. BARDA anticipates that the purified product will be formulated as a liquid formulation.

The (b)(4) doses of fill-finished drug product must be made available for clinical evaluation; the clinical trial is expected to start within (b)(4) of task order award. The Contractor must oversee storage and shipping of plasma, intermediates, and drug product between facilities as required. The Contractor must also conduct stability testing as required to support clinical use of the product.

**C. Development and Validation/Qualification of Assays to Support Screening and Manufacturing**

The Contractor shall develop assays as needed to support cGMP manufacturing, including (but not limited to) in-process, release, and stability assays. Potency assays specific to SARS-CoV-2 will need to be developed based on either wildtype SARS-CoV-2 (will require (b)(4)) or pseudotype virus (will require (b)(4)). The assays must be qualified and/or validated as appropriate using available reference standards or positive controls. This shall include the production of all analytical documentation, training and facility readiness required to support on-going testing. In the event that assays are to be subcontracted, the Contractor shall provide copies of the Supply and Quality Agreements between the Prime Contractor and Subcontractor for review prior to approval.

**D. Conduct Supportive Nonclinical Studies as Required for Development of Drug Product**

The Contractor shall conduct nonclinical studies to support the development of the human immune drug product, including any as specified by FDA. Supportive efficacy studies in animal models (e.g., mice or ferrets) may also be warranted (for example, for the submission of an EUA to FDA). In the event that studies are to be subcontracted, the Contractor shall provide copies of the Subcontractor Agreements between the Prime Contractor and Subcontractor for review prior to approval.

**E. Prepare and Submit Regulatory Filings to FDA (including IND Submission and EUA Submission)**

The Contractor shall prepare and submit regulatory filings to the FDA as required for the development and clinical use of the human immune globulin drug product, including the submission of an IND. Preliminary discussions, including (but not limited to) Pre-IND meetings, may be necessary to ensure FDA concurrence with regulatory strategy. Following the conduct of a clinical trial(s) using the drug product, the Contractor should also be prepared to support an expedited EUA submission within (b)(4) of task order award.

**F. Support clinical trial through the delivery of cGMP drug product and all supporting information as required.**

The Contractor shall support the conduct of a clinical trial evaluating the safety and efficacy of the human immune globulin drug product. BARDA anticipates that the clinical trial will be

conducted in partnership with another entity (e.g., The National Institutes of Health), who will oversee the clinical operations of the trial; the Contractor is *not* expected to manage the clinical operations of the trial. The Contractor is expected to support the clinical trials through the supply of clinical trial material as necessary (includes storage and shipping as necessary), while also providing all documentation and information as required by the study sponsor.

G. Provide program management and reporting as required

This task shall reimburse the cost for managing the contract in connection with the deliverables described in section F2. Schedule of Deliverable below. The following are examples of those typically required: project plans, tech transfer plans, protocols, validation reports, (b)(4) and final reports. Additionally, regular update meetings, ad hoc meetings, periodic site visits and (b)(4) site visits shall be included.

### OPTIONAL TASKS

**CLIN 0002 (Option): Support for Additional Clinical Trial**

A. Support clinical trial through the delivery of cGMP drug product and all supporting information as required.

The Contractor shall support the conduct of an additional a clinical trial evaluating the safety and efficacy of the human immune globulin drug product. The Contractor is expected to support the clinical trials through the supply of clinical trial material (at least (b)(4) doses) as necessary (includes storage and shipping as necessary), while also providing all documentation and information as required by the study sponsor

B. Provide program management and reporting as required

This task shall reimburse the cost for managing the contract in connection with the deliverables described in section F2. Schedule of Deliverable below. The following are examples of those typically required: project plans, tech transfer plans, protocols, validation reports, (b)(4) and final reports. Additionally, regular update meetings, ad hoc meetings, periodic site visits and (b)(4) site visits shall be included.

**D. PACKAGING AND MARKING (if applicable)**

All deliverables shall be preserved, packaged, and packed in accordance with normal commercial practices to meet the packaging requirements of the carrier, including that, which is necessary, to prevent deterioration and damages due to the hazard of shipping, handling, and storing.



## **E. INSPECTION AND ACCEPTANCE**

Inspection and acceptance of all work, performance, reports and other deliverables, under this task order, will be performed at the Contractor's facility or approved subcontractor facility, by the Contracting Officer or the duly authorized representative of the Government.

The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this task order.

## **F. PERFORMANCE / DELIVERABLES**

### **F.1 Period of Performance**

The period of performance for all optional tasks, if exercised, will fall within the Task Order award date through eighteen (18) months.

**Therefore, the entire period of performance for this task order will be eighteen (18) months from task order issuance.** Period of performance for CLINs with stability testing beyond this date will be adjusted as needed to accommodate completion.

The location of performance should be at the CIADM Contractor's U.S.-based facility, unless otherwise authorized by the Contracting Officer. Subcontractors may be offered for specific tasks (alternate facilities); however, the CIADM Contractor's capability and capacity, as outlined in the CIADM base contract, is the USG's preferred location for executing the majority of this work

### **F.2 Schedule of Deliverables**

Task	Deliverable Title	Format	Deliverable Due Dates
CLIN0001/CLIN0002			
CLIN0001/CLIN0002	Regular update teleconferences	BARDA and Contractor to determine format	First meeting will be (b)(4) post kick off meeting, subsequent meetings will be at a frequency (as short as every 2 weeks) to be agreed by the Contractor and BARDA
CLIN0001/CLIN0002	Meeting agenda and minutes for teleconferences	Contractor-determined format	Agenda – draft (b)(4) before teleconference; Minutes – draft within 3 days of teleconference
CLIN0001/CLIN0002	Monthly Status Report	BARDA-provided template	(b)(4) on (b)(4) following period
CLIN0001/CLIN0002	Integrated Master Schedule	Contractor-determined format	Within (b)(4) of contract award, updated (b)(4)



Task	Deliverable Title	Format	Deliverable Due Dates
CLIN0001/CLIN0002	Incident Report	Contractor-determined format	Notification of incident within (b)(4). Draft report within (b)(4) of incident. final report within (b)(4) of resolution
CLIN0001/CLIN0002	Quality Assurance Plan	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post contract award
CLIN0001/CLIN0002	Risk Management Plan / Risk Register	Contractor-determined format	Within (b)(4) of contract award; Risk Register updated (b)(4)
CLIN0001/CLIN0002	Detailed data regarding locations where work will be performed	Contractor-determined format	Within (b)(4) of contract award, updated (b)(4)
CLIN0001/CLIN0002	Detailed spreadsheet on critical project materials that are sourced from a location other than the United States,	Contractor-determined format	Within (b)(4) of contract award, updated (b)(4)
CLIN0001/CLIN0002	Final Task Order Report and Assessment	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post completion of task
CLIN0001/CLIN0002	Continuity of Operations Plan (to continue operations in the event of a declared pandemic emergency)	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post award of contract
CLIN0001			
CLIN0001	Plasma Collection Plan (including list of sources)	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post award of CLIN0001
CLIN0001	Reports for Plasma Collection	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post completion of task
CLIN0001	Final Manufacturing Report	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post completion of task
CLIN0001	Analytical Verification Protocols	Contractor-determined format	Draft – (b)(4) prior to planned execution Final – (b)(4) after protocol execution
CLIN0001	Analytical Reports	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post completion of task
CLIN0001	Validation Protocols	Contractor-determined format	Draft – (b)(4) prior to planned execution Final – (b)(4) after protocol execution
CLIN0001	Validation Reports	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post completion of task
CLIN0001	Fill / Finish Strategy Report	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post award of CLIN0001



Task	Deliverable Title	Format	Deliverable Due Dates
CLIN0001	Nonclinical Protocols (BARDA approval needed prior to study execution)	Contractor-determined format	Draft – (b)(4) prior to planned execution Final – (b)(4) after study execution
CLIN0001	Nonclinical Reports	Contractor-determined format	Draft – (b)(4) Final – (b)(4) post completion of task
CLIN0001	Regulatory Submissions to FDA (e.g., Meeting Requests, Briefing Books, etc.)	Contractor-determined format	Draft – (b)(4) prior to submission to FDA (or as agreed-to by the COR) Final – (b)(4) post submission to FDA
CLIN0001	Investigation New Drug (IND) Application	Contractor-determined format	Draft – (b)(4) prior to submission to FDA (or as agreed to by the COR), within (b)(4) post award of CLIN0001 Final – (b)(4) post submission to FDA
CLIN0001	Information supporting Emergency Use Authorization (EUA) Request	BARDA-determined format	Within (b)(4) of BARDA's request
CLIN0001	Documentation of drug product as requested by Sponsor of Clinical Trial	Determined by Sponsor of clinical trial	Final – (b)(4) post submission to trial sponsor
CLIN0001	Documentation of delivery of batch of fill-finished drug product for clinical trials	Determined by Sponsor of clinical trial	Final – (b)(4) post submission to trial sponsor
CLIN0001	Confirmation of cumulative availability of at least 400 doses of fill-finished drug product	Contractor-determined format	Final – (b)(4) post completion of task
CLIN0002 (Option)			
CLIN0002 (Option)	Regulatory Submissions to FDA (e.g., Meeting Requests, Briefing Books, etc.)	Contractor-determined format	Draft – (b)(4) prior to submission to FDA Final – (b)(4) post submission to FDA
CLIN0002 (Option)	Documentation of drug product as requested by Sponsor of Clinical Trial	Determined by Sponsor of clinical trial	Final – (b)(4) post submission to trial sponsor
CLIN0002 (Option)	Documentation of delivery of batch of fill-finished drug product for clinical trials	Determined by Sponsor of clinical trial	Final – (b)(4) post submission to trial sponsor
CLIN0002 (Option)	Confirmation of cumulative availability of at least 100	Contractor-determined format	Final – 2 days post completion of task



Task	Deliverable Title	Format	Deliverable Due Dates
	(additional) doses of fill-finished drug product		

## Meetings

### Routine Update Teleconferences

The CIADM shall participate in regular teleconferences with USG to discuss the performance of the task order. The frequency will be agreed upon by the CIADM and USG and may be dependent on the activities during that time of the task order. Typically, these meetings are held [REDACTED]. The CIADM shall keep meeting minutes and forward a finalized copy to the Contracting Officer (CO) and Contracting Officer's Representative (COR) for approval within [REDACTED] after each teleconference, or as otherwise authorized by the Contracting Officer.

### Person-in-Plant

CIADM shall accommodate up to [REDACTED] BARDA personnel at any given time throughout the performance of this task order. On-site BARDA personnel will provide oversight of the work and real-time technical direction per guidance from the BARDA program office in Washington, D.C.

### Periodic Site Visits

The CIADM shall accommodate for periodic site visits by USG on an *ad hoc* basis. The CIADM shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within three [REDACTED] after each site visit, or as otherwise authorized by the CO.

(b)(4)

### Site Visits

The CIADM shall provide formal presentations summarizing all work accomplished in the previous calendar quarter at the CIADM's site on a [REDACTED] basis. The CIADM shall keep meeting minutes and forward a finalized copy to the CO and COR for approval within [REDACTED] after each site visit, or as otherwise authorized by the CO.

### Kick-Off Meeting

The Contractor shall participate in a kick-off meeting, within [REDACTED] of task order award; content, format and location to be determined by the USG and the Contractor. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [REDACTED] [REDACTED] after the meeting is held, or as otherwise authorized by the Contracting Officer.

**G. CONTRACT ADMINISTRATION**

**G.1 Government Personnel**

**(a) Contracting Officer**

[Redacted]

ASPR/BARDA/CMA  
O'Neill House Office Building  
Washington, DC 20015

Email: [Redacted]  
Phone: [Redacted]

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this Task Order.

The Contracting Officer is also the only individual with authority to act as agent of the Government under this Task Order, with authority to (1) direct or negotiate any changes in the statement of work, (2) modify or extend the period of performance, (3) authorize reimbursement to the Contractor for any costs incurred during the performance of this Task Order and/or (5) otherwise change any terms and conditions of this Task Order.

**(b) Contracting Officer's Representative**

[Redacted]

ASPR/BARDA  
24H26, O'Neill House Office Building  
Washington, DC 20515

Email: [Redacted]  
Phone: [Redacted]

[Redacted]

ASPR/BARDA  
O'Neill House Office Building  
Washington, DC 20515

Email: [Redacted]  
Phone: [Redacted]



## G.2 Invoicing Instructions

Invoices for payment shall be submitted as two (2) hard copies and one (1) electronic copy to the following address, and shall include SF-1034. In addition, for Cost Plus Fixed Fee (CPFF) CLINs, the CIADM shall provide supporting documentation with the invoice to support all claimed costs. This includes an itemized breakdown of all associated costs such as labor classification, labor hours, labor rate, indirect costs, timecards, etc. This shall be provided for the CIADM (prime contractor) and all subcontractors. Further invoicing details are included in Section G of the base CIADM contract.

ASPR/BARDA/CMA  
O'Neill House Office Building  
Washington, DC 20515  
Email:   
Phone:

The Government may request additional information (timecards, receipts, etc.) to support costs claimed in the Contractor's invoices.

## G.3 Evaluation of Contractor Performance

- (a) *Purpose:* In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least  and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool ([www.cpars.gov](http://www.cpars.gov)).
- (b) *Evaluators:* The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.
- (c) *Performance Evaluation Factors:* Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).
- (d) *Contractor Review:* A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within  after receipt of the evaluation.
- (e) *Resolving Disagreements between the Government and the Contractor:* Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

- (f) *Release of Contractor Performance Evaluation Information:* The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.
- (g) *Source Selection Information:* Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.
- (h) *Retention Period:* The agency will retain past performance information for a maximum period of (b)(4) after completion of contract performance for the purpose of providing source selection information for future contract awards.

## **H. SPECIAL REQUIREMENTS**

### **H.1 Intellectual Property**

Execution of a task order may require a relationship between HHS, the firm that possesses rights to specific Intellectual Property (IP) required for the development effort (the "MCM IP Holder"), and the firm providing the Core Services under the task order (the "CIADM"). The relationship must reflect the Parties' rights to all IP developed and/or IP used in performance of the task order, and be consistent with HHS' IP rights per the Federal Acquisition Regulations (FAR) clauses described in the base contract. Prior to any performance of work, the MCM IP Holder and/or the CIADM shall provide the Contracting Officer with a written description of all IP necessary to develop (the "Description"). The Description must identify the basis for offering HHS less than unlimited rights to any pre-existing IP identified in the Description that will be utilized in performance of the task order. The Description shall also include written verification of the rights provided to HHS to any and all IP utilized or developed during performance of the task order as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract and/or teaming agreement related to performance of the task order, FAR Clause 52.227-14 and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement (the "FAR Clauses").

The MCM IP Holder and the CIADM will remain free to negotiate any agreement of their own regarding their use of any of the IP utilized or developed during performance of an task order, so long as the negotiated agreement complies with the requirements under the FAR Clauses, and the terms contained in the agreement do not otherwise adversely affect the performance of work under the task order. The agreement shall be furnished to the Contracting Officer within (b)(4) after the agreement is finalized. In addition, this task order incorporates FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).



## H.2 Key Personnel

Key personnel specified in this task order are considered to be essential to work performance. At least 30 days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts, the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement, and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than 30 day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace or announce any such change to key personnel without the written consent of the Contracting Officer. The task order will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individuals are determined to be key personnel. The offeror may list other individual(s) it deems would fall under the Key Personnel category, for USG evaluation.

Name	Title
(b)(6)	

## H.3 Personnel Qualifications

The offeror shall provide curriculum vitae (CV) for each individual specified in its proposal as key personnel. The CV shall clearly describe the individual's knowledge, work experiences, registrations, and certifications, and applicable experience. The CV shall include a summary describing the individual's involvement in similar work.

## H.4 Consultants and Sub-Contractors

If the Contractor determines that the use of Subcontractors or Consultants is needed, the Contractor is directed to submit a Contracting Officer's Authorization request.

## **H.5 No Personal Services or Inherently Governmental Function**

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government Contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of this contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

## **H.6 ADDITIONAL TERMS AND CONDITIONS**

The terms and conditions applicable to this Task Order Award are as follows:

### **References:**

- Base Contract Number: HHSO100201200004I
- Task Order (TO) Award Number: 75A50120F33006
- HHS reserves the right to exercise priorities and allocations authority with respect to this task order, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

### **Documents Incorporated By Reference:**

1. Proposal dated March 20, 2020
2. Revised price proposal dated March 31, 2020



**I. FAR/HHSAR CONTRACT CLAUSES**

**I.1 52.232-2 Clauses Incorporated by Reference**

All clauses incorporated in the base contract are in full effect at the task order level. This section or other parts of this TOR may incorporate one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. In addition, the full text of a clause may be accessed electronically at this address:

<https://www.acquisition.gov/>